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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,472	03/26/2001	Wilson Smart	Kum11Si1.Prb	6422

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Kumetrix Inc.
29524 Union City Blvd.
Union City, CA 94587

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/816,472

Applicant(s)

SMART ET AL

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 34, 36-50, 57, 58, 60, 64, 65 and 67 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 48-50 and 58 is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-31, 34, 36, 37, 57, 60, 64, 65, 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-18-06</u> | 6) <input type="checkbox"/> Other: _____ |

Claims 28-30 and 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The examiner notes that the declaration filed 9/18/2006 is defective for several reasons. First, it is only signed by Mr. Smart. MPEP 715.04 all inventors must sign the 1.131 declaration unless there is a showing that the inventor signing was the inventor of the claims at issue. No such showing has been made here. As such, the declaration is defective. Second, Exhibit C does not show the biosensor and exhibit d is not specific as to what probe the sensor is on. As such, applicant has not proved that the invention of claim 1 and 67 has been reduced to practice prior to the date of Frasier.. Third, there is no showing of a microfillet portion of claim 11, so there is no showing that claim 11 has been reduced to practice prior to Frasier. Fourth, there is no showing of the sensor in a cavity. Accordingly, there is no showing that claim 48 has been reduced to practice prior to Frasier. Fifth, there is no showing of a sensor on each side of the probe, so there is no showing that the device of claim 50 was reduced to practice prior to Frasier. Sixth, it is unclear whether the silicon in exhibit C is single crystal silicon. Seventh, applicant has tried to establish diligence from conception to reduction to practice. However, diligence requires a showing specific dates and activities with all periods, no matter how small, being accounted for. This is clear not the case in the current declaration, so no showing of diligence has been made.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-15, 18, 19, 20-27, 31, 34, 36-37, 50, 60, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al WO 01/93930 in view of Pisano et al 5928207 and Say 6134461. Frazier et al shows a microneedle having a silicon substrate (see page 8, line 10) and has a body portion 18 and a penetration portion 11, with a biosensor 17 mounted on the penetration portion. It does not state whether the silicon is single crystal silicon. Pisano is one of several references that teach that it is well known to manufacture microneedles from single crystal silicon (see columns 7 and 8, example 1). Hence, it would have been obvious to modify Frazier et al to use single crystal silicon, as it is merely the selection of a well-known silicon for the identical purpose. Say further teaches a device where the sensor is at the penetration end and is connected to the body portion via wires. As such, there is no closed channel. Therefore, it would have been obvious to modify the above combination to use such a structure, as it is merely the substitution of one known equivalent configuration for another. With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the X direction. With respect to claims 5-8 and 60, the substrate has the recited dimensions (see columns 9 and 10). With respect to claim 9, Say et al shows a chisel shaped microneedle.

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Therefore, it would have been obvious to modify Frazier et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure discussed in column 7, lines 21-26 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. With respect to claim 13, Frazier does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify the above combination to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. Claims 14 and 15 are rejected in that Frazier can use a electrochemical sensor. Claim 18 is rejected in that the microneedle of Pisano has an electrically insulation silicon dioxide layer 92 on the substrate. Claim 19 is rejected in that it is an silicon dioxide film. Claims 21-24 are rejected in that applicant has admitted that the techniques recited are well known techniques used to deposit contacts on a substrate and therefore it would have been obvious to modify the above combination et al to use the recited techniques. Claim 25 is rejected in that the sensor is optical. Claim 26 is rejected in that the sensor is spaced enough from the body portion to penetrate into the body. Claim 27 is rejected in that the sensor is "near" the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claims 34 and 36 are rejected in that there are multiple biosensors and different x dimension depths. Claim 37 is rejected in that the substrate is single crystal silicon.

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Claim 50 is rejected in the, in addition to the reasons given above, there are multiple biosensors sensing multiple parameters. Claim 69 is rejected as discussed above.

Claims 69-70 are met by incorporating the structure of Say.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Say et al, as applied above, further in view of in view of Meade et al 5770369. Meade teaches that electrogravimetric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravimetric sensor, as it is merely the substitution of one known equivalent for another.

Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Say, as applied above, further in view of in view of Lin et al 5855801. Lin et al shows electrical components on a silicon dioxide insulation layer of a microneedle. Hence, it would have been obvious to modify the above combination to use such an arrangement, as it is merely the substitution of one known equivalent arrangement for another.

Claims 57, 64, and 65 are rejected is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Pisano et al and Lin et al and Say et al. The Frazier/Pisano combination does not teach the relative thicknesses of the needle and body 18. Lin et al teaches that the body is thicker than the needle (see column 4, lines 21-35). Hence, it would have been obvious to modify the above combination to make the body thicker than the needle, as it is merely the substitution of one known equivalent configuration for another. In addition, Say teaches an alternate construction of a similar

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device that has a uniform thickness. As such, it would have been obvious to modify the above combination to have a uniform thickness, as it is merely the substitution of one known equivalent construction for another. With respect to claims 64 and 65, the dimensions are taught by Frazier on page 9.

Claims 11, 48-50 and 58 are allowable. Claim 11 defines over the art in that none of the art teaches the microfillet portion. In view of the discussion on page 12 of the specification, it is clear that the inclusion of such a portion is more than merely a change in shape and therefore defines over the art of record. Claims 48, 49, and 58 define over the art in that none of the art shows the biosensor in a cavity on the substrate. Claim 50 defines over the art of record in that none of the art shows multiple biosensors on multiple sides of the substrate, as claimed.

Applicant's arguments filed 10/29/2006 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant has asserted that Frazier uses a bioluminescence sensor. The examiner notes that Frazier uses several types of sensors, including electrochemical sensors (see column 6, line 12, and column 7, lines 1-12).

Applicant has asserted that to modify Frazier to use a sensor at the penetration end and thereby eliminate the closed fluid channel would destroy Frazier's operating principle, since Frazier teaches that the channel enhances optical transmission and act as a waveguide. The examiner first notes that Frazier does not require an optical sensor and neither do the claims. Therefore, it is the examiner's position that this

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argument is only relevant to claim 25, as the same issues would not present with all of the sensors recited.

As far as claim 25 is concerned, applicant has argued that using an optical sensor in the position of Say would render the sensor useless, as the light would be lost in the body. The examiner disagrees, and note that reflective optical sensors are well known in this field, where light is emitted into a sample and the reflected light is analyzed to measure a physiological parameter.

Applicant has further asserted that Say does not teach that the substrate may be single crystal silicon, like some of applicant's claims. The examiner notes that the Federal Circuit has clearly established that a reference is good for all it teaches. Here, say teaches the positioning of the sensor on a substrate.

With respect to claims 56, 64, and 65, applicant has individually attacked the reference. The rejection is a combination rejection and the test is not what each reference lacks, but what the combination shows. Here, it is the examiner's position that the combination shows the uniform thickness in the claimed range, as discussed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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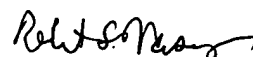
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser



ROBERT L. NASSER
PRIMARY EXAMINER

Art Unit: 3735

Primary Examiner
Art Unit 3735

Rln
January 7, 2006